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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,058	12/07/2001	David Reginald Adams	20791	7827

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HOFFMANN-LA ROCHE INC.
PATENT LAW DEPARTMENT
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EXAMINER

BERNHARDT, EMILY B

ART UNIT PAPER NUMBER

1624

DATE MAILED: 01/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/010,058

Applicant(s)

ADAMS ET AL.

Examiner

Emily Bernhardt

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 and 35-44 is/are pending in the application.
- 4a) Of the above claim(s) 36,37,43 and 44 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14-32 is/are allowed.
- 6) ☒ Claim(s) 1-13,33,35,38-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

In view of applicants' response filed 9/24/03 the following applies.

Applicants indicate that the claims have been amended to conform to Group I subject matter. However, applicants should note that the species deleted from claim 14 is part of Group I subject matter. Applicants request rejoinder of claims 36,37, 43 and 44 but the request is denied. New rejoinder rules pertain to use claims employing only compounds commensurate in scope with allowed subject matter and not to claims containing additional active ingredients. The IDS of 9/29/03 is a duplicate of one already considered by the examiner, namely the IDS of 4/15/03. The examiner's comment in the last office action was directed to the existence of an IDS filed **earlier** than 4/15/03. Note on the first page of the 4/15/03 IDS it is stated that an earlier IDS was filed on 2/27/02. This IDS is not seen in the file.

Claims 1-9, 12,13, 33,35 and 38-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. The first proviso on p.4 in claim 1 is now extraneous due to the deletion of nitro as a choice for substituents on aryl at A2.

2. The inclusion of certain "optional substituents" for aryl/cycloalkyl when these rings are further fused in claims 1,2 is unclear as to intended scope. These

substituents are already recited for said fused rings at the end of the fused ring definition unless another definition is being provided but its not clear for what.

Claims 1-10,12,13,33,35,38-42 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The scope of substituents permitted on A2 rings remains nonenabled. Contrary to what applicants urge reasoning has been given in making this rejection which include factors considered in the Wands decision discussed at length in the MPEP as set forth in the last office action. In the absence of any data for species presumed tested, there can be no evaluation of structure-activity trends. Note the following quote taken from *In re Cauvallito* 127 USPQ 202 cited in *Surrey*, which was previously cited, at p.206, left column: "On the other hand, wide variation in such potency would suggest that it was due in part to the added substituents and might be eliminated or even reversed by many of the possible substituents which had not been tried." .

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4,7,9-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Toldy. The para-Cl benzyl ester still reads on the instant claims notwithstanding applicants' amendments to the claims. Halo is a choice for substituents on phenyl in A2.

The 102 rejections over Aicher and Kawamoto are overcome in view of the amendments to the scope of A2 which can no longer be unsubstituted phenyl or NO₂-substituted phenyl. However, the following rejection pertains to the amended scope.

Claims 1-4,7,9,10,12 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Ishida (abstract for JP'671 provided). The reference teaches a compound within the instant scope as a precursor to carbapenem derivatives. See 4-methoxyphenyl methyl ester compound depicted in the abstract.

Claims 14-32 remain allowed .


This application contains claims 36,37,43 and 44 drawn to an invention nonelected with traverse in Paper No. 7. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication should be directed to Emily Bernhardt at telephone number (703) 308-4714.

A facsimile center has been established for Group 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The new fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.


EMILY BERNHARDT
PRIMARY EXAMINER
GROUP 1600